REMARKS/ARGUMENTS

Claims 19 and 20 are under consideration in the instant application.

New claims 27-29 have been added.

Rejections Under 35 U.S.C. §102

The Examiner has rejected claims 19 and 20 under 35 U.S.C, 102, second paragraph, as being anticipated by Pines et al (US 5,852,024).

The Examiner states that claims 19 and 20 are drawn to a method of improving liver regeneration by increasing IGFBP-1 expression in hepatocyte cells, comprising administering a compound of the formula of claim 19 (e.g. halofuginone). The Examiner further states that Pines et al teaches that the adminsitration of halofuginone following surgery or other trauma to the liver promotes healing of the organ. According to the Examiner, although Pines et al does not explicitly teach that this method improves liver regeneration by increasing IGFBP-1 expression, this activity is an inherent property of halofuginone, and is necessarily present.

Pines et al does not disclose the amount of the compound of the present invention which is required to improve liver regeneration. As taught on page 4, lines 23 to 27, liver fibrosis and cirrhosis are dynamic processes that can both progress and regress over time. It is essential for improvement of liver regeneration that the amount of the compound of claim 19 administered is sufficient to increase IGFBP-1 expression to a level which at least increases the rate of resolution over the rate of liver damage progression. Claim 19 has been amended to specify the amount of the compound used in the method of the present invention.

New claim 27, dependent from claim 19, has been added, reciting that the method of the present invention specifically induces hepatoctye cells, thereby further delimiting the method to cells of hepatocyte origin due to specific activity in the liver.

New claim 28, dependent from claim 19, has been added, reciting that the method of the present invention inhibits stellate cell motility, as supported by the

specification at page 21, lines 20 to 26. Such an effect on stellate cells was neither taught nor suggested by the prior art.

New dependent claim 29 has been added, reciting that administration is performed early in the liver damage process. Support for such a claim is derived from the specification at page 17, lines 15 to 17, which teach that IGFBP-1 is an immediate-early gene induced after liver damage, and resulting in liver regeneration.

The present response is intended to be fully responsive to all points of objection raised by the Examiner and is believed to place claims 26 to 29 in condition for allowance. Favorable reconsideration and allowance of the Application is respectfully requested.

CONCLUSION

Applicant believes that the claims are in condition for allowance. If the Examiner believes that a telephonic interview with the undersigned would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned at (301) 952-1011.

Respectfully submitted,

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